

CLAIMS

1. A pharmaceutical composition for prevention or inhibition of progression of diabetic complication, which is prepared for administration before meal and comprises mitiglinide or a pharmaceutically acceptable salt thereof, or a hydrate thereof, wherein the amount to be administered as a single dose is 5 to 45 mg.
2. A pharmaceutical composition as claimed in claim 1 wherein the composition is prepared for administration just before meal.
3. A pharmaceutical composition as claimed in claim 1 or 2 wherein the composition is to be administered three times a day before each meal for 4 weeks or more.
4. A pharmaceutical composition as claimed in any of claims 1 to 3 wherein the amount to be administered as a single dose is 5 to 22 mg.
5. A pharmaceutical composition as claimed in claim 4 wherein the amount to be administered as a single dose is 10 to 11 mg and the active ingredient is mitiglinide calcium salt hydrate.
6. A pharmaceutical composition as claimed in any of claims 1 to 5 wherein the dissolution time for 75% release in the first fluid of the Japanese Pharmacopoeia is 20 minutes or less.
7. A pharmaceutical composition as claimed in any of claims 1 to 6 wherein the diabetic complication is diabetic microvascular complication.
8. A pharmaceutical composition as claimed in claim 7 wherein the diabetic microvascular complication is diabetic

retinopathy.

9. A pharmaceutical composition as claimed in claim 7 wherein the diabetic microvascular complication is diabetic nephropathy.

5 10. A pharmaceutical composition as claimed in any of claims 1 to 6 wherein the diabetic complication is arteriosclerotic diseases.

11. A method for prevention or inhibition of progression of diabetic complication, which comprises administering before
10 meal 5 to 45 mg of mitiglinide or a pharmaceutically acceptable salt thereof, or a hydrate thereof as a single dose.

12. A method for prevention or inhibition of progression as claimed in claim 11 wherein the single dose is 5 to 22 mg.

13. A method for prevention or inhibition of progression as
15 claimed in claim 12 wherein the single dose is 10 to 11 mg and the active ingredient is mitiglinide calcium salt hydrate.

14. A method for prevention or inhibition of progression as claimed in any of claims 11 to 13 wherein the number of doses a day is three.

20 15. A method for prevention or inhibition of progression as claimed in any of claims 11 to 14 wherein the treatment period is 4 weeks or more.

16. A use of mitiglinide or a pharmaceutically acceptable salt thereof, or a hydrate thereof for the manufacture of a
25 pharmaceutical composition as claimed in any of claims 1 to 10.